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10/565,537	01/19/2006	Michael Melkonian	1020-018US01	9911
28863	7590	10/25/2007	EXAMINER	
SHUMAKER & SIEFFERT, P. A.			KIM, TAEYOON	
1625 RADIO DRIVE			ART UNIT	PAPER NUMBER
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WOODBURY, MN 55125			MAIL DATE	DELIVERY MODE
			10/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/565,537	MELKONIAN ET AL.
	Examiner Taeyoon Kim	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 August 2007.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 18-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 18-30 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Claims 18-30 are pending.

Response to Amendment

Applicant's amendment and response filed on Aug. 20, 2007 has been received and entered into the case.

Claims 1-17 are canceled, claims 18-30 are newly added, and have been considered on the merits. All arguments have been fully considered.

The claim rejection under 35 U.S.C §102 based on Halling et al. is withdrawn due to the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "plastic fibers" in claim 20 is not supported by the specification, and thus the term introduces a new matter situation to the application. Appropriate action is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies et al. (US 4,693,983) in light of Chaverot et al. (US 5,445,473).

Claims 18-28 are drawn to a method for cultivating eukaryotic microorganisms comprising providing a perforated support having first and second major surface wherein the support being a sheet-shaped material and being impermeable to eukaryotic microorganisms or blue algae, applying the eukaryotic microorganisms or blue algae to the first major surface wherein the microorganisms being immobilized, flowing an aqueous solution along the first major surface, wherein the flowing aqueous solution being transported to the first major surface by capillary forces, and the eukaryotic microorganisms or blue algae grow on the first major surface (claim 18); a limitation to the aqueous solution forming a distributing layer to distribute the solution across the second major surface of each perforated support (claim 19); a limitation to the distributing layer being a non-woven material comprising glass or plastic fibers (claim 20); a limitation to the distributing layer comprising a geotextile (claim 21); a limitation to the support and/or the distributing layer being hydrophilic (claims 22-24); a limitation to the support and the distributing layer comprising hydrophilic organic fibers (claims 25-27); a limitation to the method further comprising additional support identical configuration of the support, wherein two supports having the second major surface facing each other and arranged being in parallel to each other, and the aqueous

solution being introduced and flowing between the two supports in contact with the second surfaces (claim 28).

Davies et al. teach a method using a reactor for cultivating plant or animal cells. The reactor of Davies et al. comprising a perforated support having two channel (surface) wherein biological materials (plant or animal cells) bound to walls of first channel impermeable to the material, and the liquid and/or gas (nutrients) are transferred between the first channels and the second channels through porous walls (see Fig. 1 and column 2, lines 1-18). The transferred of liquid (nutrients) through the porous walls is inherently carried out by capillary forces because Davies et al. teach the porous wall having a capillary connection between channels (see. Fig. 4). The bioreactor of Davies et al. comprises multiple channels formed and first major surfaces (channels where cells are immobilized) face each other and share with one second major surface (channel) whereby liquid can flow between two facing first major surfaces (see Fig. 1). Furthermore, the matrix support of Davies et al.'s bioreactor is made of ceramic material, which has been leached in an acid or alkali to render the interior walls porous (see column 3, lines 47-50). Davies et al. also disclose porous cells being treated with a semi-permeable membrane such as cellulose acetate, which inherently hydrophilic (distribution layer of a non-woven material) (see column 3, lines 57-61). Davies et al. also disclose a reactor being constructed according to corrugation-reinforced cardboard sheet technology (see column 6, lines 3-11), therefore, the support of the reactor being considered as sheet-shaped.

Although Davies et al. do not particularly teach "geotextile" for the support, the

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layer of cellulose acetate used as a coating to the support/reactor of Davies et al. (see column 3, lines 57-61) is inherently considered as a geotextile because Chaverot et al. disclose that cellulose acetate as a source of geotextile (see column 2, lines 23-33).

Thus, the reference anticipates the claimed subject matter.

In the response to the previous office action, applicant argued that the method of Davies et al. do not disclose or suggest any method for cultivating eukaryotic microorganisms or blue algae that uses a sheet-shaped perforated support, and referred to the Fig. 1 of Davies et al. As discussed above, Davies et al.'s support (not only that of Fig. 1 also Fig.3) is considered to be sheet-shaped, and thus the method of using such support of Davies et al. anticipates the currently claimed invention.

Applicant also argued that Davies et al. do not suggest supplying an aqueous solution to a second major surface of the sheet-shaped perforated support. This is not persuasive because there are two major compartment (channels) in the support, which are considered as two major surfaces, wherein cells are grown in the first channel, and the liquid and/or gas, thus nutrient is transferred between the first channels and the second channels across the porous walls (see column 2, lines 13-18). Further, Davies et al. disclose that the transfer of the nutrient would be driven by capillary force (see column 6, lines 49-57).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (supra).

Claims 18-30 are drawn to a method for cultivating eukaryotic microorganisms comprising providing a perforated support having first and second major surface wherein the support being a sheet-shaped material and being impermeable to eukaryotic microorganisms or blue algae, applying the eukaryotic microorganisms or blue algae to the first major surface wherein the microorganisms being immobilized, flowing an aqueous solution along the first major surface, wherein the flowing aqueous solution being transported to the first major surface by capillary forces, and the eukaryotic microorganisms or blue algae grow on the first major surface (claim 18); a limitation to the aqueous solution forming a distributing layer to distribute the solution across the second major surface of each perforated support (claim 19); a limitation to the distributing layer being a non-woven material comprising glass or plastic fibers

(claim 20); a limitation to the distributing layer comprising a geotextile (claim 21); a limitation to the support and/or the distributing layer being hydrophilic (claims 22-24); a limitation to the support and the distributing layer comprising hydrophilic organic fibers (claims 25-27); a limitation to the method further comprising additional support identical configuration of the support, wherein two supports having the second major surface facing each other and arranged being in parallel to each other, and the aqueous solution being introduced and flowing between the two supports in contact with the second surfaces (claim 28); a limitation to the method further comprising a step of removing the eukaryotic microorganisms or blue algae from the support by mechanical forces (claim 29) or chemical treatment (claim 30).

Davies et al. anticipate the subject matter of claims 18-28, and thus render them obvious (see above).

Although Davies et al. do not particularly teach a step of harvesting in the method in claim 29, it would have been obvious for a person of ordinary skill in the art to recognize the need of harvesting cells grown in the bioreactor of Davies et al. by using mechanical forces. In fact, Davies et al. teach that cells grown in a first major surface can be removed by flushing (see column 4, lines 57-62), indicating that the step of harvesting cells grown in Davies et al.'s bioreactor can be mechanically collected from the support matrix.

Although Davies et al. do not particularly teach the step of harvesting cells by chemical treatment as in claim 30, it would have been obvious to a person of ordinary skill in the art to optimize the step of harvesting cells because a person of ordinary skill

in the art would recognize such step of harvesting cells is a result effective variable. As such, the variables would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by those references. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%); >see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); ** *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d

1362 (Fed. Cir. 1997). Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Claims 18, 19 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halling et al. (WO 90/02170).

Claims 18, 19 and 22-24 are drawn to a method for cultivating eukaryotic microorganisms comprising providing a perforated support having first and second major surface wherein the support being a sheet-shaped material and being impermeable to eukaryotic microorganisms or blue algae, applying the eukaryotic microorganisms or blue algae to the first major surface wherein the microorganisms being immobilized, flowing an aqueous solution along the first major surface, wherein the flowing aqueous solution being transported to the first major surface by capillary forces, and the eukaryotic microorganisms or blue algae grow on the first major surface (claim 18); a limitation to the aqueous solution forming a distributing layer to distribute the solution across the second major surface of each perforated support (claim 19); a limitation to the support and/or the distributing layer being hydrophilic (claims 22-24).

Halling et al. teach a method and an apparatus (membrane bioreactor) for culturing microbial cells (plant and animal cells) immobilized on the outside (shell side; first major surface) of a membrane through which a culture medium can flow (inside of

the membrane; tube side; second major surface), and through a support matrix surrounding the membrane (see Abstract, p.1, line 3; p.1, line 33-p.2, line 3; p.2 line 36 to p.3, line 4; and Fig. 1-3). The material of perforated support of Halling et al. is a macroporous ceramic material (see p.2, line 5), which is inorganic and inherently hydrophilic.

Although Halling et al. do not teach the support being sheet-shaped, it would have been obvious to a person of ordinary skill in the art because there is a legal precedent that the change of shape in a material used in the invention would be obvious to a person of ordinary skill in the art in the absence of persuasive evidence to prove the significance of such shape in the invention.

M.P.E.P. §2144.04 states "In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.)"

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

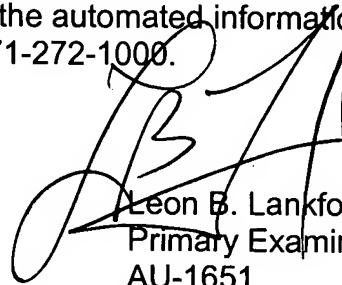
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 9:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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